[*TXR # 0011636*
17-AUG-1995]

MEMORANDUM

SUBJECT ***DICAMBA--DIGLYCOLAMINE & ISOPROPYLAMINE SALTS*****:**
Core Data for Toxicology Data Requirement § 82-2.

FROM: Jess Rowland, M.S, Toxicologist
Section II, Toxicology Branch II, Health Effects Division (7509C)

TO: Walter Waldrop/Jane Mitchell
Product Manager 71, Reregistration Division

THRU: K. Clark Swentzel, Head
Section II, Toxicology Branch II, Health Effects Division (7509C)
and
Karl Baetcke, Ph.D., Acting Chief
Toxicology Branch II, Health Effects Division (7509C)

TASK IDENTIFICATIONS: Submission: S482621 DP Barcode: D212548

PC Code(s): 128931 (Dicamba-DGA) 128944 (Dicamba-IPA)

ACTION REQUESTED: Review the 21-day dermal toxicity studies with the diglycolamine [MRID No. 435542-06] and the isopropylamine [MRID No. 435542-07] salts of dicamba submitted to satisfy toxicology data requirement §82-2.

RESPONSE: Data Evaluation Reports for the above mentioned studies are attached and the Executive Summaries are as follows:

1. *"A REPEATED DOSE (21-DAY) DERMAL TOXICITY STUDY OF DGA SALT OF DICAMBA IN THE RABBIT" (Study ID #94-2326).*

EXECUTIVE SUMMARY: In a 21-day dermal toxicity study (MRID No. 435542-06) New Zealand White rabbits [5/sex/dose] were given repeated dermal applications of the diglycolamine salt (59%) of dicamba at 0, 100, 500 or 1000 mg/kg, 6 hours/day, 5 days/week for a total of 15 applications during a 3 week period. No treatment-related dermal reactions or histopathological dermal lesions were seen. No systemic toxicity was seen; treatment had no adverse effect on survival, clinical signs, mean body weights, body weight gains, hematology, clinical chemistry, organ weights or gross and histopathology. **Based on the results of this study, a NOEL of 1000 mg/kg/day (Limit-Dose) was established for both dermal irritation and systemic toxicity. A LOEL was not established for either end-point.**

CORE CLASSIFICATION: This study is classified as **Core Guideline** and satisfies the data requirement [§82-2] for a 21-day dermal toxicity study in rabbits and is acceptable for regulatory purposes.

2. *"A REPEATED DOSE (21-DAY) DERMAL TOXICITY STUDY OF IPA SALT OF DICAMBA IN THE RABBIT" (Study ID # 94-2327).*

EXECUTIVE SUMMARY: In a 21-day dermal toxicity study (MRID No. 435542-07) New Zealand White rabbits [5/sex/dose] were given repeated dermal applications of the isopropylamine salt (41%) of dicamba at 0, 100, 500 or 1000 mg/kg, 6 hours/day, 5 days/week for a total of 15 applications
during a 3 week period. No treatment-related dermal reactions or histopathological dermal lesions were seen. No systemic toxicity was seen; treatment had no adverse effect on survival, clinical signs, mean body weights, body weight gains, hematology, clinical chemistry, organ weights or gross and histopathology. **Based on the results of this study, a NOEL of 1000 mg/kg/day (Limit-Dose) was established for both dermal irritation and systemic toxicity. A LOEL was not established for either end-point.**

CORE CLASSIFICATION: This study is classified as **Core Guideline** and satisfies the data requirement [§82-2] for a 21-day dermal toxicity study in rabbits and is acceptable for regulatory purposes.